

**Before the
Federal Communications Commission
Washington, D.C. 20554**

In the Matter of)	
)	
Investigation of the Spectrum Requirements)	ET Docket No. 06-135
for Advanced Medical Technologies)	
)	
Amendment of Parts 2 and 95 of the)	RM-11271
Commission's Rules to Establish the Medical)	
Device Radio Communications Service at)	
401-402 and 405-406 MHz)	

REPLY COMMENTS OF ST. JUDE MEDICAL

St. Jude Medical, Inc. and its wholly-owned subsidiary, Advanced Neuromodulation Systems, Inc. (collectively, "St. Jude Medical"), hereby support two rule changes requested in the Petition for Reconsideration ("Petition") filed by Medtronic, Inc. ("Medtronic") in the above-captioned proceeding.¹ In particular, the FCC should revise its MedRadio rules to (i) permit MedRadio transmit power to be measured on the basis of average power and (ii) permit use of the human torso simulator and measurement technique that was previously allowed under the MICS rules.² As explained below, these changes will serve the public interest and avoid possible violation of the Administrative Procedure Act ("APA").

¹ Petition for Reconsideration of Medtronic, Inc., ET Docket No. 06-135, RM-11271 (June 15, 2009) ("Petition").

² St. Jude takes no position on the other rule changes or clarifications requested in the Petition.

I. DISCUSSION

St. Jude Medical applauds the Commission for adopting the landmark *MedRadio Order* earlier this year.³ By creating new opportunities for wireless medical technologies at 401-406 MHz, the *MedRadio Order* promises to “significantly improve the quality of life and sophistication of therapy for countless Americans living with a variety of medical conditions.”⁴ St. Jude Medical is confident that this promise can be realized, but agrees with Medtronic that two of the *MedRadio* rules as currently written may thwart the FCC’s goals and therefore should be modified upon reconsideration.

First, the Commission should continue to permit *MedRadio* transmit power to be measured on the basis of average power. As Medtronic points out, average power measurements were permitted under the prior MICS rules,⁵ and neither the Commission nor any party proposed changing this provision during the *MedRadio* rulemaking proceeding. Nonetheless, the *MedRadio Order* deleted section 95.639(f)(1), which permitted average power measurements, and added a new rule, section 95.628(g)(3), which requires use of a peak power measurement technique. St. Jude Medical agrees with Medtronic that mandating exclusive use of peak power measurements would drastically reduce the transmit power (and system range) available to certain systems. These constraints would thwart technological innovation and improvement in patient care

³ *Investigation of the Spectrum Requirements for Advanced Medical Technologies; Amendment of Parts 2 and 95 of the Commission’s Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz; DexCom, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules; Biotronik, Inc., Request for Waiver of the Frequency Monitoring Requirements of the Medical Implant Communications Service Rules*, Report and Order, 24 FCC Rcd 3474 (2009) (“*MedRadio Order*”).

⁴ *MedRadio Order* ¶ 2.

⁵ See 47 C.F.R. § 95.639(f)(1) (2008).

– precisely the opposite of what the Commission sought to achieve in the *MedRadio Order*.⁶ Furthermore, as Medtronic argues, because the new peak-power rule was not the subject of notice and comment as required by the APA, the rule appears to be arbitrary and capricious and therefore unlawful.⁷ For these reasons, the Commission should grant Medtronic’s request that the MedRadio rules be modified to allow use of an average power measurement technique, as previously permitted under the MICS regime.

The Commission also should reinstate the human torso simulator, tissue material, and test technique provisions that previously obtained under the MICS rules.⁸ Former section 95.639(f)(2)(i) permitted the use of specific human torso measurement techniques for implantable transmitters.⁹ The FCC deleted this technique from the MedRadio rules, mandating instead that measurements “be made in accordance with a Commission-approved human body simulator and test technique.”¹⁰ St. Jude Medical agrees with Medtronic that reinstating the torso simulator and test technique as an option in the MedRadio rules would be useful for device manufacturers that relied on the prior test configuration in developing equipment. The torso simulator and test technique is widely recognized internationally, and its deletion from the MedRadio rules – like that of the average-power rule – appears to have occurred without the prior notice and comment that the APA requires. The Commission therefore should reinstate, as an option in the

⁶ See, e.g., *MedRadio Order* ¶ 16.

⁷ See 5 U.S.C. § 553(b).

⁸ See Petition at 5-7.

⁹ See 47 C.F.R. § 95.639(f)(2)(i) (2008).

¹⁰ 47 C.F.R. § 95.628(g)(3)(i).

MedRadio rules, the torso simulator and test technique previously available to device manufacturers under the MICS rules, as modified slightly by Medtronic.¹¹

II. CONCLUSION

St. Jude Medical respectfully urges the Commission to reconsider and modify its MedRadio rules to the extent requested above.

Respectfully submitted,

/s/ Richard D. Mallen

Richard D. Mallen
Lawler, Metzger, Keeney & Logan, LLC
2001 K Street NW, Suite 802
Washington, DC 20006
(202) 777-7700
rmallen@lawlermetzger.com

Counsel for St. Jude Medical

Kathleen M. Chester
Senior Vice President, Regulatory Affairs
and Quality Assurance
St. Jude Medical Cardiac Rhythm
Management Division

Kimberley Elting
Vice President and General Counsel
Advanced Neuromodulation Systems, Inc.
d/b/a St. Jude Medical Neuromodulation Division

August 21, 2009

¹¹ See Petition at 7 and Appendix A (proposing modifications to section 95.639(f)).

Certificate of Service

I hereby certify that on this 21st day of August, 2009, I caused true and correct copies of the foregoing Reply Comments of St. Jude Medical to be mailed by first class U.S. mail, postage prepaid, to:

Robert L. Pettit
David E. Hilliard
John W. Kuzin
Wiley Rein LLP
1776 K Street NW
Washington, DC 20006
Attorneys for Medtronic, Inc.

Laura Stefani
Henry Goldberg
Goldberg, Godles, Wiener & Wright
1229 19th Street NW
Washington, DC 20036
Attorneys for Biotronik, Inc.

/s/ Ruth E. Holder
Ruth E. Holder